

Five Year Effectiveness and Treatment Survivorship of an Implantable Shock Absorber (ISA) for Patients with Medial Knee Osteoarthritis (OA)

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INTRODUCTION:

Patients suffering from functionally limiting symptoms of medial knee osteoarthritis (OA) represent a significant treatment challenge for orthopaedic surgeons. Many of these patients have failed non-surgical treatment and are not yet candidates for, or are reluctant to undergo, joint replacement, leaving few effective and durable options in this treatment gap. The two-year clinical benefit and superiority of an ISA over high tibial osteotomy (HTO) in this challenging patient population has been established and previously reported. In the current study we report the 5-year effectiveness and durability of the ISA procedure in this difficult, pre-arthroplasty patient population.

METHODS:

An IRB-approved, multi-center, prospective clinical trial enrolled and evaluated eighty-one (81) ISA patients and compared safety and efficacy of the procedure to 81 patients treated with HTO. At two years, the groups were compared for safety and efficacy of treatment. Annual follow-up on the ISA patients continued through 5 years to evaluate longer-term effectiveness and treatment survivorship of the ISA procedure, defined here as freedom from conversion to joint replacement or HTO.

RESULTS: Eighty-one (81) knee OA subjects, aged 51.2 ± 7.71 years (range 33 – 64) and with a BMI of 28.4 ± 3.45 and baseline KL of 2.5 (range 1-4), were treated with an ISA. ISA treatment demonstrated sustained effectiveness through five years and a low incidence of conversion to joint replacement or HTO. At 5-year follow-up, eight (8/81, 9.9%) patients underwent a conversion to either primary arthroplasty (7, 8.6%) or HTO (1, 1.2%) resulting in a 90.1% (73/81) treatment survivorship at five years. Clinically meaningful improvement (defined as 20% and 10-point absolute improvement from baseline) in WOMAC pain scores were reported by 95.7% of the patients, with a mean improvement of 43.4 (SD 19.7) points or 72.0% from preoperative baseline scores. Functional improvements were also sustained through five years in 85.7% (defined as 20% and 10-point absolute improvement from baseline) of patients with a mean improvement of 42.1 (SD 21.83) points or 68.0% from baseline. Through the entire five-year follow-up period, one patient (1.2%) exhibited mechanical failure of the ISA device requiring removal.

DISCUSSION AND CONCLUSION: At five years, the ISA demonstrated sustained pain relief and functional improvement for medial knee OA patients previously caught in the treatment gap. In addition to these benefits and high rates of survivorship reported here, the study demonstrated the ability of the ISA to preserve all standard downstream surgical options (HTO, arthroplasty) through 5 years. Conversions were performed in both staged and single-procedure fashion, using standard arthroplasty technique and primary components. The potential of the ISA to meaningfully delay premature joint replacement is supported by high levels of treatment survivorship and low mechanical failure rates found in this study. Based upon these data and prior reports, the ISA is a proven and established solution for patients with medial compartment osteoarthritis.

